

### **AMENDMENTS TO THE SPECIFICATION**

Please replace the paragraph at p. 10, lines 17-22, of the specification with the following paragraph:

Other useful hydrophilic or water-miscible vehicles may be polyvinylpyrrolidones, polyvinyl-polyvinylacetate copolymers (PVP-PVA), polyvinyl alcohol (PVA), polymethacrylic polymers (Eudragit® RS; Eudragit® RL, Eudragit® NE, Eudragit® E), cellulose derivatives including hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, pectins, cyclodextrins, galactomannans, alginates, carragenates, xanthan gums and mixtures thereof.

Please replace the paragraph at p. 12, lines 5-19, of the specification with the following paragraph:

Examples on suitable fillers, diluents and/or binders include lactose (e. g. spray-dried lactose,  $\alpha$ -lactose,  $\beta$ -lactose, Tabletose®, various grades of Pharmatose®, Microtose®; or Fast-Floc®, microcrystalline cellulose (various grades of Avicel®, Elcema®, Vivacel®, Ming Tai® or Solka-Floc®), hydroxypropylcellulose, L-hydroxypropylcellulose (low substituted), hydroxypropyl methylcellulose (HPMC) (e. g. Methocel® E, F and K, Metolose® SH of Shin-Etsu, Ltd, such as, e. g. the 4,000 cps grades of Methocel E and Metolose® 60 SH, the 4,000 cps grades of Methocel® F and Metolose® 65 SH, the 4,000, 15,000 and 100,000 cps grades of Methocel® K; and the 4,000, 15,000, 39,000 and 100,000 grades of Metolose® 90 SH), methylcellulose polymers (such as, e. g., Methocel® A, Methocel® A4C, Methocel® A15C, Methocel® A4M), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylene, carboxymethylhydroxyethylcellulose and other cellulose derivatives, sucrose, agarose, sorbitol, mannitol, dextrins, maltodextrins, starches or modified starches (including potato starch, maize starch and rice starch), calcium phosphate (e. g.

basic calcium phosphate, calcium hydrogen phosphate, dicalcium phosphate hydrate), calcium sulfate, calcium carbonate, sodium alginate, collagen etc.

Please replace the paragraph at p. 21, lines 13-29, of the specification with the following paragraph:

Other suitable oils or oily-like materials may be solvents or semi-solid excipients like, e. g. propylene glycol, polyglycolised glycerides including Gelucire® 44/14, complex fatty materials of plant origin including theobroma oil, carnauba wax, vegetable oils like e. g. almond oil, coconut oil, corn oil, cottonseed oil, sesame oil, soya oil, olive oil, castor oil, palm kernels oil, peanut oil, rape oil, grape seed oil etc. , hydrogenated vegetable oils such as, e. g. hydrogenated peanut oil, hydrogenated palm kernels oil, hydrogenated cottonseed oil, hydrogenated soya oil, hydrogenated castor oil, hydrogenated coconut oil ; natural fatty materials of animal origin including beeswax, lanolin, fatty alcohols including cetyl, stearyl, lauric, myristic, palmitic, stearic fatty alcohols ; esters including glycerol stearate, glycol stearate, ethyl oleate, isopropyl myristate; liquid interesterified semi-synthetic glycerides including Miglycol Miglyol® 810/812; amide or fatty acid alcolamides including stearamide ethanol, diethanolamide of fatty coconut acids, acetic acid esters of mono and di-glycerides, citric acid esters of mono and di-glycerides, lactic acid esters of mono and diglycerides, mono and di- glycerides, poly-glycerol esters of fatty acids, poly-glycerol poly-ricinoleate, propylene glycol esters of fatty acids, sorbitan monostearates, sorbitan tristearates, sodium stearyl lactylates, calcium stearoyl lactylates, diacetyl tartaric acid esters of mono and di-glycerides etc.

Please replace the paragraph at p. 25, lines 7-12, of the specification with the following paragraph:

Suitable water soluble carriers include polymers such as polyethylene glycol, poloxamers, polyoxyethylene stearates, poly-s-caprolactone, polyvinylpyrrolidone (PVP), polyvinylpyrrolidone-polyvinylacetate copolymer PVP-PVA (Kollidon® VA64), poly-methacrylic polymers (Eudragit® RS, Eudragit® RL, Eudragit® NE, Eudragit® E) and polyvinyl alcohol (PVA), hydroxypropyl cellulose (HPC), hydroxypropyl methyl cellulose (HPMC), methyl cellulose, and poly (ethylene oxide) (PEO).

Please replace the paragraph at p. 29, lines 11-14, of the specification with the following paragraph:

Either tablets, capsules or granules might be enteric coated with different types of polymers such as hydroxypropylmethylcellulose acetate succinate (Aqoat), cellulose acetate phthalate CAP, hydroxypropylmethylcellulose phthalate HPMCP or methacrylic acid copolymers such as Eudragit® L30D, Eudragit® 100/S, Eudragit® 100/L.

Please replace the paragraphs at p. 33, lines 1-14, of the specification with the following paragraphs:

### EXAMPLE 3

#### Enteric coating of immediate release tablets of example 2

The enteric coating is based on the acrylic polymer Eudragit® L30D-55. Eudragit® L30D is supplied as an aqueous latex suspension creating a water insoluble film when the water is evaporated during coating. The polymer is insoluble at pH-values below 5.0 and readily soluble at

pH-values above 6.0. The tablets prepared as described in example 2 were coated with the following film coating composition:

Substance	w/w%
Eudragit® L30D-55	40
Water	52
Triethyl citrate	1.8
Anti-foam emulsion	0.2
Talc (micro)	6
Total	100

The amount of applied film polymer (Eudragit®) is based on a calculation of mg film polymer per cm<sup>2</sup> of tablet surface. The thickness of the enteric coating was 80 p. m. A verification of the film-thickness applied was based on measuring the increase in tablet height with a digital micrometer. The film coating process was performed in a Phast FB100 fluid bed equipped with a Wurster like insert using an inlet air temperature of 50°C, inlet air flow of 100 cbm per hour, product temperature of 38°C and feed rate 15 g/min.

Please replace the paragraph at p. 36, line 21, of the specification with the following paragraph:

Relative bioavailability based on AUC (invention vs. Prograf®): 742%